

### **Effectum Medical AG**

assists in the development of innovative medical devices and technologies throughout the certification and life cycle management process. Acting as legal manufacturer and by offering our Plug & Play (e)QMS, we speed up your time to market and ensure compliance and excellence in every stage of development.

### EFFECTUM MEDICAL

# PLUG & PLAY (e)QMS BOOTCAMP



# OVERVIEW ALL SERVICES

Plug & Play (e)QMS Bootcamp – Overview	3
Plug & Play (e)QMS Bootcamp Spring 2025	4
Plug & Play (e)QMS Bootcamp Spring 2025 Training Schedule	5
Self-Study Plug & Play (e)QMS Bootcamp	6
Self-Study Plug & Play (e)QMS Bootcamp Training Schedule	7
Support Option	8



# PLUG & PLAY (e)QMS BOOTCAMP OVERVIEW

#### Plug and Play (e)QMS Bootcamp

Enhance your (e)QMS management and technical documentation skills with our Plug & Play (e)QMS Bootcamp. Choose between our hybrid Spring 2025 Bootcamp or the self-study option for flexible learning at your own pace. Our Bootcamp is ideal for companies using or planning to purchase our Plug & Play (eQMS) SOP Packages.

#### Self-Study Bootcamp Includes:

- Self-Study Modules: Five detailed modules to build your QMS expertise.
- 1-on-1 Q&A Sessions: Schedule an hour with an expert after each module.
- **12 Months Free Access:** Revisit content anytime with access to Effectum's e-Learning platform and additional training videos.

#### Spring 2025 Hybrid Bootcamp Includes:

- Expert-Led Modules: Six workshops (2-4 hours each) over three weeks.
- Flexible Participation: Join workshops on-site or remotely and network with other companies.
- Six Months Free Access to additional training materials.

Earn a certificate upon completion. Connect, learn, and grow with Effectum's Plug & Play (e)QMS Bootcamp!



**Camilla Messerli** Head Quality Management & Regulatory Affairs camilla.messerli@effectummedical.com



# PLUG & PLAY (e)QMS BOOTCAMP SPRING 2025

#### Plug & Play (e)QMS Bootcamp March / April 2025

- 1. Get to know our process experts and take the opportunity to ask your questions to the (e)QMS Management and your journey from Technical Documentation until CE certification and Post Market Surveillance.
- 2. Receive training including a training certificate on Effectum's (e)QMS and get to know how the SOP's and templates work. This will greatly facilitate your path to certification.
- 3. Get 6-months free access to Effectum's e-learning platform to update your know-how when it is needed.
- 4. Enjoy 6-months free access to our **monthly online lunch sessions** held by **Effectum's team members and key partners** to share best practices, trends and latest insights on relevant topics for your venture's journey.
- **5.** Join interactive workshops over three weeks, connecting with like-minded medical device startups. Attend on-site at Effectum Medical in Olten, Switzerland, or remotely.

This Bootcamp is designed for companies having purchased our QMS SOP package.

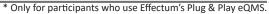
Sign up for Qualio eQMS by January 31st, 2025 to be ready for the Bootcamp!

If you are part of one of our parntner programs, please reach out to us to learn more about or partnership offering. (Our partner:<u>www.effectummedical.com/partners/</u>)



# PLUG & PLAY (e)QMS BOOTCAMP SPRING 2025 TRAINING SCHEDULE

Dates 2025	Торіс
<b>March 26,</b> 10h00-12h00	Qualio eQMS Intro*
13h00-16h00	<b>QMS – General</b> quality manual, management responsibilities, document management, human resources, training, internal audits, CSV etc.
March 27,	QMS: Design & Development - Part I
13h00-17h00	design & development process / technical documentation (TD) / verification & validation; product classification, applicable regulatory requirements, software lifecycle process
March 31,	QMS: Design & Development - Part II
13h00-17h00	risk management, clinical evaluation (MD) vs. performance evaluation (IVD)
<b>April 03,</b> 09h00-12h00	QMS: Design & Development - Part III usability engineering, labelling requirements/UDI, design review meetings, TD management, change management, TD submission EU/CH/USA & Launch Phase
April 09,	QMS: Supplier Management and Product Release
08h30-12h00	supplier handling & control, quality agreements, purchasing, incoming inspection, production, storage, packing, process validation, product release
April 11,	QMS: Non-Conformities and PMS
09h00-12h00	corrective and preventive actions, complaints, post market surveillance (PMS), vigilance
13h00-15h00	Qualio eQMS Management*





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### SELF-STUDY PLUG & PLAY (e)QMS BOOTCAMP

#### Join Our Self-Study Plug and Play QMS Bootcamp!

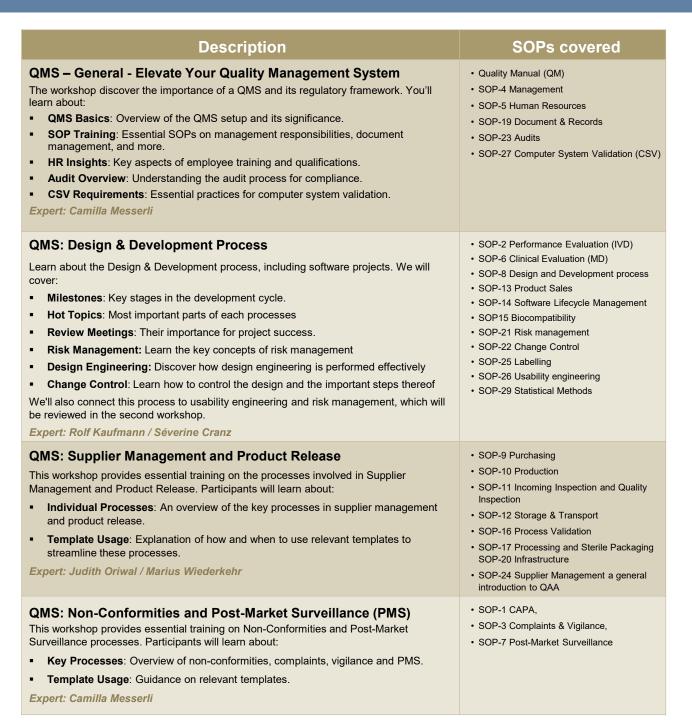
- 1. Learn at your own pace and dive into the various aspects of (e)QMS management. Our Bootcamp consists of five comprehensive modules, each designed to enhance your understanding and skills in quality management systems.
- 2. After completing each module, you can schedule a 1h Q&A session with the respective expert to clarify any questions and deepen your insights.
- 3. Enjoy **twelve months of free access to Effectum's e-Learning platform**, allowing you to update your knowledge whenever needed and allowing you to access some other videos, not directly part of the Bootcamp.
- 4. Additionally, participate for six months in our **monthly online lunch sessions** hosted by Effectum team members and key partners. These sessions are a great opportunity to exchange best practices, trends, and the latest insights on relevant topics for your business.
- 5. Upon completion of the Bootcamp, you will receive a **certificate and course confirmation to showcase** your achievement.

Unlock your potential in quality management with us-enroll today!

This Bootcamp is designed for companies having purchased our QMS SOP package.

Price (excl documents): 2000.- CHF per user, every additional user of your company gets a 50% discount if they sign up at the same time and the Q&A sessions are performed together!

### SELF-STUDY PLUG & PLAY (e)QMS BOOTCAMP TRAINING SCHEDULE



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#### **Outsourced Legal Manufacturer:**

Streamline market access and compliance with our trusted legal manufacturer services. Need speed? Ask about our fast-track option!



#### Plug & Play (e)QMS:

Accelerate your launch with a ready-made EN ISO 13485, MDR/IVDR, and FDA-compliant quality management system.



### Plug-and-Play eQMS Bootcamp:

Flexible training to empower self-management of your QMS.



#### Rent an Expert:

Add quality management and regulatory expertise to your team as needed.



#### **Regulatory Opinions:**

Access expert insights for global compliance and market strategy.



#### AI/ML Device Certification:

Certification services for AI and machine learning-based medical devices.

#### CH-REP (Swiss Authorized Representative):

CH REP

Facilitate Swiss market access with local representation. Visit <u>Effectum CH-REP AG</u> for details.

For more information visit: www.effectummedical.com



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8

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